ANDA 091465

Sandoz Inc.
Attention: Alison Sherwood
Manager, Regulatory Affairs
2555 W. Midway Blvd
P.O. Box 446
Broomfield, CO 80038

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 7, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexmedetomidine Hydrochloride Injection, 100 mcg (base)/mL, packaged in 200 mcg/2 mL Single-use Vials (Preservative-Free).

Reference is also made to your amendments dated December 28, 2009; May 18, July 12, and August 18, 2010; and March 7, 2011.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Precedex HCl Injection, 100 mcg (base)/mL of Hospira Inc., is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

| U.S. Patent Number | Expiration Date |
|---|---|
| 5,344,840 (the '840 patent) | September 6, 2011 |
| 4,910,214 (the '214 patent) | July 15, 2013 |
| 6,716,867 (the '867 patent) | March 31, 2019 |

With respect to the '840 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Sandoz will not market Dexmedetomidine Hydrochloride Injection, 100 mcg (base)/mL prior to the expiration of this patent. Final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act prior to the expiration of the '840 patent.

With respect to the '214 and '867 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Dexmedetomidine Hydrochloride Injection, 100 mcg (base)/mL, under this ANDA. You notified the agency that Sandoz Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '214 and '867 patents was brought against Sandoz within the statutory 45-day period in the United States District Court for the Northern District of New Jersey and the District of Delaware [Hospira Inc. and Orion Corporation v. Sandoz International GmbH and Sandoz Inc., Civil Action Nos. CV-04591-MLC-TJB and CV-00665-UNA, respectively].

Therefore, final approval cannot be granted until the '840 patent has expired and:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),

   b. the date the court decides[1] that the '241 and '867 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act) or,

   c. the listed patents have expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed

[1] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

drug also will be required to have a REMS. See section 505-1(i) of the Act.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this application, or prior to submitting additional amendments, please contact Benjamin Danso, Pharm.D, Regulatory Quality Project Manager, at (240) 276-8527.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ROBERT L WEST

03/15/2011

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.